



UNITED STATES PATENT AND TRADEMARK OFFICE

M
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/038,984

01/04/2002

Yin-Xiong Li

275.0003 0102

9705

26813

7590

04/20/2006

MUETING, RAASCH & GEBHARDT, P.A.

P.O. BOX 581415

MINNEAPOLIS, MN 55458

EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/038,984	Applicant(s) LI ET AL.	
	Examiner Tracy Vivlemore	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, 72-76 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, 72-76 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

The indicated allowability of claims 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, 72-74 and 78-81 is withdrawn in view of the following rejection.

Claim Rejections - 35 USC § 102

Claims 1-7, 15-19, 22, 28-32, 39, 62, 63, and 72-76 and 78-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559, of record).

The claimed invention is directed to methods of attenuating gene expression in an embryonic fish cell by administration of double stranded RNA. In specific embodiments the fish cell is from a zebrafish and the target gene is endogenous, foreign, chromosomal or from a pathogen. The double stranded RNA can be formed from one strand or two complementary strands and may be at least 25 nucleotides in length or may be less than 200 bases in length.

Fire et al. disclose a method of inhibiting gene expression using a double stranded RNA. Fire et al. disclose that the method is general and can be performed in fish. Fire et al. also disclose at column 9, lines 44-48 that the method can be performed in embryos. The genes targeted can be endogenous or a transgene, which is a foreign gene, or can be from a pathogen (see column 6, lines 45-49). Fire et al. disclose the

Art Unit: 1635

limitations on hybridization conditions and length at column 7, line 67-column 8 line 6 and the dsRNAs used in the disclosed examples were purified without phenol and chloroform. The dsRNA can be formed from 1 or 2 strands (see column 4, lines 41-46). The method of Fire et al. can be used to treat disease and the dsRNAs can be delivered via several different means (see column 9, lines 48-64).

Thus, Fire et al. disclose all the limitations of and anticipate claims 1-7, 15-19, 22, 28-32, 39, 62, 63, and 72-76 and 78-81.

Response to arguments

Applicant traverses the previous 102 rejection of claims 75 and 76 over Fire et al. by asserting that Fire et al. do not disclose all limitations of these claims, specifically the recitation of explanting and implanting the vertebrate cell. These limitations are disclosed at column 10, lines 12-14: "The inhibitory RNA could be introduced in cells in vitro or ex vivo and then subsequently placed into an animal to affect therapy...". Applicant further states that Fire et al. do not disclose purification without phenol and chloroform. This argument is not persuasive because, as stated in the previous office action, the dsRNAs used in the exemplified embodiments were purified without phenol and chloroform.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, and 72-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. as applied to claims 1-7, 15-19, 22, 28-32, 39, 62, 63, and 72-76 and 78-81 above, and further in view of Kreutzer et al. (US 2005/0100907).

Claims 1-7, 15-19, 22, 28-32, 39, 62, 63, and 72-76 and 78-81 are described in the previous 102 rejection. Claims 27 and 48 recite the limitation that the double stranded RNA is treated with RNase prior to administration to a cell.

Fire et al. teach a method of inhibiting gene expression using double stranded RNA. Fire et al. teach that the method is general and target organisms include embryos and fish. The genes targeted can be endogenous or a transgene, which is a foreign gene, or can be from a pathogen. The dsRNA can be formed from 1 or 2 strands and can be produced by expression from a plasmid, the method can be used to treat disease and the dsRNAs can be delivered via several different means. Fire et al. do not teach the use of RNase to purify the double stranded RNA prior to administration.

Kreutzer et al. teach a method of inhibiting gene expression using double stranded RNAs that are produced by expression from a plasmid. Kreutzer et al. teach at page 4, paragraph 48, that RNases specific for single strand RNAs but not double stranded RNAs are used to remove contaminating single stranded RNA from their dsRNA preparations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fire et al. of a method of inhibiting gene expression with double stranded RNAs that can be produced from plasmid expression and the teaching of Kreutzer et al. of production of RNA from plasmids followed by removal of contaminating single stranded RNA using RNases. One of ordinary skill in the art would have been motivated to produce the dsRNA from a plasmid because of the ease of synthesis of RNA from plasmids and would have been

Art Unit: 1635

motivated to remove the single stranded contaminants as taught by Kreutzer et al. in order to produce a pure preparation of RNA. One of ordinary skill in the art would have had a reasonable expectation of success in purifying double stranded RNA by treatment with RNase because Kreutzer et al. actually teach production of dsRNA using this procedure.

Thus, the invention of claims 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, and 72-76 and 78-81 would have been obvious, as a whole, at the time of invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

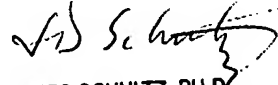
Art Unit: 1635

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
April 4, 2006


JAMES SCHULTZ, PH.D.
JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER